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U.S. DISTRICT COURT
N.D. OF ALABAMA

Exhibit C

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IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE

KATRINA DAWN COPLEY
Plaintiff
v.
BAYER HEALTHCARE PHARMACEUTICALS, INC.
Defendant.

: Civil Action No.: 3:14-CV-00406

Friday, April 29, 2016

Washington, D.C.

VIDEOTAPED DEPOSITION OF:
DENA R. HIXON, M.D.

a witness in the above-entitled cause, called for examination by counsel for the Defendant, pursuant to notice and to agreement of counsel as to time and place, at the offices of Covington & Burling LLP, One CityCenter, 850 Tenth Street, N.W., Washington, D.C. 20001, commencing at 9:13 a.m., before Samara J. Zink, a Notary Public in and for the District of Columbia, when were present on behalf of the respective parties:

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A P P E A R A N C E S

ON BEHALF OF THE PLAINTIFF:
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ON BEHALF OF THE DEFENDANT:
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ALSO PRESENT:
Larry Newman, videographer

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C O N T E N T S

E X H I B I T S
(Attached to transcript)

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P R O C E E D I N G S

THE VIDEOGRAPHER: We are now on the record. My name is Larry Newman. I am a videographer for Golkow Technologies. Today's date is Friday, April 29th, 2016. The time is 9:13 a.m. This video deposition is being held in Washington, D.C. in the matter of Katrina Dawn Copley versus Bayer Healthcare, et al., and this is in the United States District Court for the Middle Division of

Tennessee, Nashville Division. Our deponent is Dena Hixon.

Would our counsel please identify themselves.

MR. JONES: Larry Jones for the Plaintiffs.

MS. NATALE: Christina Natale for the Plaintiffs.

MR. IMBROSCIO: Michael Imbroscio for Bayer.

MS. PALEY: Kathleen Paley for Bayer.

THE VIDEOGRAPHER: Our court reporter today is Samara Zink and will now swear in the witness.

Whereupon,

DENA R. HIXON, M.D.

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a Witness, called for examination by counsel for the Plaintiffs, having first been duly sworn, was examined and testified as follows:

EXAMINATION BY COUNSEL FOR PLAINTIFFS

BY MR. JONES:

Q. Good morning. I'm Larry Jones.

A. Good morning.

Q. Will you please state your full name for the record.

A. Dena R. Hixon.

MR. IMBROSCIO: And, Larry, before you begin, I just want to make a note. We've also cross-noticed this deposition in the other cases where Dr. Hixon has issued a report, the cases that are in discovery, and we'll have those attached to the end of the deposition as well. I know you're not probably accepting them or whatever the case may be, but I want to just note for the record that we've cross-noticed this in the other cases.

MR. JONES: Yeah. And when you say "the other cases" -- I know I saw some -- are they the ones that Dr. Hixon has --

MR. IMBROSCIO: Yes.

MR. JONES: -- issued a report in?

MR. IMBROSCIO: Correct. Yes.

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MR. JONES: Okay. Fair enough.

BY MR. JONES:

Q. And as I said, Dr. Hixon, you are a

medical doctor, correct?
A. Yes, I am.
Q. Okay. And you issued a report in this litigation and several other -- or this case and several others, as counsel has noted, correct?
A. The others -- it was one single report for the other cases.
Q. Okay. Do you know which cases you've issued a report for?
A. So I have issued the one report for this case, and the other cases were the cases related to uterine perforations with Mirena.
Q. Okay. Let me -- let me clarify. There -- your report -- let's talk about this particular case --
A. Okay.
Q. -- the Copley case.
You've issued -- you've submitted a 37-page report --
A. Correct.
Q. -- correct?
Okay. And have you -- are you aware that

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you have submitted the same 37-page report in other cases involving benign intracranial hypertension?
A. I -- I am not specifically aware, but that seems correct based on our background discussions.
Q. Okay. And do you know the names of any of my clients that you've issued reports in their particular cases?
A. No, I do not.
Q. Okay. I note in your report, you say that you were paid -- you were compensated at a rate of $600 per hour for reviewing materials and creating this report; is that correct?
A. That's correct.
Q. Okay. And do you have an additional rate that you receive for testifying?
A. No. I charge the same rate for everything.
Q. Okay. Doctor, I'm going to hand you what we're going to mark as Deposition Exhibit 1.
(Exhibit 1 was marked for identification and is attached to the transcript.)
THE WITNESS: Thank you.
BY MR. JONES:
Q. This is a Notice of Video Deposition of Dena Hixon, M.D. Have I represented the document

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that's been handed to you correctly?
A. Yes.
Q. Okay. And have you seen this before?
A. Yes.
Q. Okay. And you'll note beginning back on page 4 that there's several document requests where it says "Documents to Be Produced." Do you see that?
A. That's correct.
Q. Okay. And did you review each of these 20 requests?
A. Yes, I did.
Q. Okay. And what did you -- did you gather any documents pursuant to these 20 requests?
A. I did.
Q. Okay. And what did you do to look for the documents that have been requested in these 20 items?
A. I went through the list and I noted, for instance, that the curriculum vitae had already been presented to the attorneys. I went through my archived documents to find presentations and talks, and I provided to the attorneys the ones that I found.
Q. Okay.

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MR. IMBROSCIO: And, Larry, we have a set of stuff -- I probably should have done this before and I forgot -- in response. We're happy to hand it over and have her walk you through it, whatever the case may be.
MR. JONES: Yeah, if you could just hand it over. Just if you could give it to Christina and she'll start looking through things.
MS. PALEY: This is a copy of presentations. Here are the IIH invoices.
MR. JONES: Can I see the IIH invoice?
THE WITNESS: To finish my answer, I also --
BY MR. JONES:
Q. Yes, ma'am.
A. -- looked at the rest of the -- the requests and found that a number of them were not applicable. I -- I didn't have anything to respond to them. And everything that I had I provided to

the attorneys.
Q. Thank you.
Okay. Doctor -- excuse me -- among the materials that have just been handed across the table, I see two invoices from Pharmaceutical Life -- Lifecycle Consulting, LLC. What is

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Pharmaceutical Lifecycle Consulting, LLC?
A. I work as a single-member LLC, and my business is called Pharmaceutical Lifecycle --
Q. Okay.
A. -- Consulting, LLC.
Q. Okay. And on the two invoices, I see a billing for February 2016 and March 2016. Did you do any work on this case before February 2016?
A. No, I did not.
Q. And the February 2016 invoice notes that you spent 24 hours, 40 minutes for a grand total of $14,800. Does that sound correct?
A. Yes, it does.
Q. And the March invoice notes that you spent 32 hours and 30 minutes: Mirena litigation document review, discussions with attorneys, and drafting report. Does that sound correct?
A. Yes, it does.
Q. I'm going to try my math skills here.
So is it fair to say that between February and March of 2016, you were paid $34,300 for -- from Bayer for your work involved with this case?
A. That's correct.
Q. And did you do any work on this case in April 2016?

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A. Yes, I did. And I haven't added up my hours worked in April at this point.
Q. Okay. Approximately how many hours would you think that would be?
A. I'm not sure. My best guess would be around 40 hours.
Q. Around 40 hours.
So 40 hours times $600 an hour would be approximately another $24,000?
A. That sounds right.
Q. And you're getting paid for your -- you're getting paid for your time to appear here today for your deposition, correct?

A. That's correct.
Q. And that's at $600 an hour as well?
A. That's correct.
Q. So by my calculations, we would be at approximately $54,300 before your testimony here today. Does that sound like it is about correct?
A. That sounds like it's in the ballpark.
Q. Okay. And you mentioned that you were a -- I think you said the sole member of Pharmaceutical Lifestyle Consulting, LLC?
A. Lifecycle Consulting. Yes.
Q. What did I say?

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A. You said --
Q. Lifestyle?
A. -- lifestyle.
Q. Sorry.
A. That's okay.
Q. So you don't have any partners in that?
A. No, I do not.
Q. Okay. And when did you form Pharmaceutical Lifecycle Consulting, LLC?
A. I believe it was actually formed in December of 2011. I didn't start doing any work until 2012.
Q. And other than litigation consulting, have you ever done any work for Bayer Healthcare Pharmaceuticals?
A. I don't believe so. Nothing comes to mind that I've done for Bayer.
Q. And you are also -- you've also been designated as an expert witness and have done work in the Mirena migration perforation MDL, correct?
A. That's correct.
Q. And approximately how much money have you been paid for your work in the migration perforation MDL?
A. As best I recall, somewhere between 150-

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and $200,000.
Q. And was that all in 2015, or does that -- have you done work in 2016 that you would bill for?
A. That was 2014 and '15.
Q. Okay. Now, in preparing your report to be submitted in this litigation, did you use any portions of the report that you submitted in the

migration perforation MDL?
A. I -- I used some of the same information, yes.
Q. Okay. My question is a little different.
Did you use -- did you, for instance, copy things out of the MDL report and paste them into the report for this case?
A. I think there were some general sections that I did copy into this report. I didn't do so without reviewing them to be sure that they were appropriate as they were written.
Q. Right. It makes sense. I'm not attacking you on it. There's no sense in recreating the wheel.
A. Right.
Q. I'm just trying to figure out what you spent on this particular case.
Also in your report you list lots

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of different -- it's -- your report is footnoted; is that correct?
A. That's correct.
Q. Okay. And let's see how many footnotes you go to.
I'm counting 235 footnotes to this report. Does that sound about correct?
A. I think that's probably accurate.
Q. Okay. And when we say "footnote," that means you're citing to a particular document for support for the proposition that you've put in your report?
A. That's correct.
Q. Okay. And --
A. It's also for providing additional information if needed. So --
Q. Okay. And explain that to me.
A. -- it doesn't necessarily mean that that's where all of my information comes from because I'm acquiring that background not only from other documents but also based on my experience and knowledge.
Q. Okay. Well, let me ask you this. Are all the opinions that you are intending to give at the trial in this case contained within the body of your

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37-page report?

A. Yes, they are.
Q. And back to the footnotes. It looks like it contains a potpourri of materials we'll call it. It looks like some FDA guidances; is that correct?
A. Correct.
Q. Statutory citations; is that correct?
A. That's correct.
Q. Medical journal articles?
A. That's correct.
Q. Bayer internal documents?
A. That's correct.
Q. FDA regulations?
A. Correct.
Q. And did you review all of these materials prior to preparing your report?
A. Prior to and during the preparation of the report. Some of them I put into the report as I went along and others were reviewed before I started the writing process.
Q. Fair enough.
I guess my question is more at the time that you signed your signature on this report, is it fair to say that you had reviewed all of the

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documents listed in these footnotes?
A. Yes.
Q. Okay. And then also we received a list of materials that you reviewed but perhaps didn't rely on. Is that fair to say?
A. That's correct.
Q. Okay. And those -- when we -- when I say "not relied on," I mean they're not specifically cited in your report?
A. That's correct.
Q. Okay. And that -- those materials are -- are kind of the same types of materials, internal documents, medical journal articles, et cetera, correct?
A. That's correct. And I must say that it includes some of the deposition transcripts related to this case. And some of those transcripts I did not review in detail.
Q. Okay. Well, let's talk about just what's in your -- in your report here.
A. Okay.
Q. In the 235 footnotes, did you review all of the documents that you cited in detail?

MR. IMBROSCIO: Object to the -- object to the form.

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MR. JONES: That's fine.
BY MR. JONES:
Q. Do you understand what I mean?
A. I understand what you mean. And I -- I reviewed those. I -- I certainly didn't commit them to memory, and I -- I did more than skim them. So I would say that I thoroughly reviewed them.
Q. Well, let me ask the question a different way.
Each of the documents cited in your 235 footnotes, did you review those documents from cover to cover?
A. I believe there may have been some information in those that I -- I didn't read, like some of the references and -- and footnotes and so forth, but I at least went through them from cover to cover.
Q. Putting aside the footnotes that may have been in the individual documents that are contained in your footnotes to your report, did you review each document? Did you read every word on each document?
A. No, I did not read every word on each document. I reviewed them the same way I would have reviewed them in preparing reviews when I worked at

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FDA.
Q. Okay. And when you worked at FDA, did that include not reviewing footnotes that are contained in documents that were submitted?
MR. IMBROSCIO: Object to the form.
THE WITNESS: When I said "footnotes," I basically -- for instance, I didn't go through the entire list of -- of references, that sort of thing. But, yes, I looked at the footnotes.
BY MR. JONES:
Q. Do you think it's important when you're reviewing a document to read the references and follow those references through to make sure that the authors have accurately characterized what -- what they've represented in their papers?
A. It depends on the situation and -- and what their references are. I mean, no, I don't

think it's important to read every footnote or every reference to document.
Q. But you agree that in both this case and when you worked at the FDA, we're dealing with patient safety issues, right?
A. That's correct.
Q. But you don't think that it's important to review the references contained in footnotes?

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MR. IMBROSCIO: Object to the form. Argumentative.
THE WITNESS: I think I've explained that I reviewed those documents and the necessary detail to be able to form my opinions and write my report.
BY MR. JONES:
Q. Now, the documents that you reviewed that were not footnoted in your report, why did you not include those in your report?
A. Because in writing the report, I was looking for information that would be relevant to what I was writing and would provide additional information that the reader might want to see. And the other documents provided insight and background and understanding and information for me but were not necessarily information that I felt needed to be in the report.
Q. You mentioned that you reviewed some deposition transcripts?
A. That's correct.
Q. Which depositions did you review?
A. I reviewed Dr. Ross' deposition. I reviewed quite a few others. Walsh. I don't have a list of all those depositions in front of me, so --
Q. As we sit here today, can you recall any

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depositions that you reviewed other than Walsh and Dr. Ross?
A. Fraunfelder to -- to some extent. I -- I briefly looked at Etminan. I looked at Plouffe. I can't remember all the other names. There was Connor or Korner or maybe both and other company witnesses that I'm not specifically remembering their names because I'm not particularly familiar with them.
Q. Okay. And did you -- any of these depositions that you reviewed, did you review

them from the beginning to the end reading every page?
A. Some of them I did and some of them I didn't.
Q. Which ones did you review from the first page to the last page?
A. Particularly Dr. Ross and numerous ones of the company witnesses as well.
Q. Well, this is my only time to ask you the questions. So which of the numerous company witnesses --
A. Well, would you like to --
Q. Hold on. May I finish my question?
This is my only time to ask you about

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this. So would you be able to tell me as you sit here today which of the company witnesses you reviewed their transcripts from the first page to the last page?
A. If you can provide me with the document that lists all of their names, I can do that.
Q. From memory, you can't remember?
A. Look, I don't remember all of those names. I remember the concepts. If you -- if I see the documents, it will help me. But, no, I didn't sit down and memorize a list of names.
Q. How did you decide which deposition transcripts you were going to review in this case?
A. I looked through them to see, you know, who they were and what the person's responsibilities were. And I read as many of them as I could get through.
Q. Are you confident that you've been provided with every deposition transcript that relates to this case?
A. I believe so.
Q. And why do you believe so?
A. Because the attorneys carefully sent me deposition transcripts and I haven't known of anything that I haven't been provided with. And my

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perception is that I've had a very complete supply of depositions and other information to read and review.
Q. How did you decide which Bayer internal documents you were going to review in this case?

A. Based on some depositions that I had reviewed for the previous cases and understanding who those people were and their positions at -- at Bayer and how relevant their testimony would be to my report and my opinions.
MR. IMBROSCIO: I think he's asking you about documents, not depositions.
MR. JONES: I think she was answering to documents.
BY MR. JONES:
Q. Weren't you?
A. Oh, I'm sorry. I was answering depositions.
Q. Oh, okay.
A. Forgive me.
I read the vast majority of the documents because it was important for gathering the information.
Q. The vast majority of what documents?
A. Of all of the documents that I've listed.

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Q. Okay. And so my question is, how did you select which documents to review for this case?
A. I made every attempt to review all of them.
Q. Do you know how many documents -- how many pages of documents have been produced in the benign intracranial hypertension cases?
A. Thousands.
Q. Just thousands?
A. Well, probably hundreds of thousands. I -- I'm fully aware of what's in an NDA and what's in an IND. And I have read the information that is relevant to the discussion at hand. And I have read -- excuse me -- the communications that were produced, and there's -- you know, I can't think of anything specific that I haven't reviewed.
Q. Do you have access to a Bayer database of the documents that Bayer has produced to Plaintiffs in this case?
A. To a Bayer database. I'm not sure that I have access to a Bayer database. I have been provided access to a -- a huge number of documents, including NDA and IND documents and post-marketing reports and communications. So I have looked at a huge amount of documents.

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Q. And did the attorneys send you the documents to review?
A. Yes.
Q. Okay.
A. And in addition to what the attorneys sent me, I looked for additional information as I went along if there was something I felt that I needed more information on.
Q. Would it surprise you to learn that there have been over 10 million pages of documents produced in this case?
A. That doesn't surprise me at all.
Q. And have you had access to all 10 million pages of documents?
A. Quite honestly, I haven't added up the number of documents and the number of pages that I have, but anything that I would have asked for was provided to me.
Q. I know you haven't added up the pages, but can you tell me if you've had access -- that you've had access to over 10 million pages of documents?
A. I think that -- I think I have.
Q. Did you review over 10 million pages of documents?
A. No, I didn't review over 10 million pages

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of documents, because having worked at FDA, I'm very aware of the kinds of information that are not relevant to the kind of work that -- that I was doing here.
There are hundreds of thousands of pages of chemistry, manufacturing, and controls information. There are many thousands of pages of information on clinical pharmacology and biopharmaceutics. I certainly had information on clinical data. I had information on the preclinical data. And there certainly is a huge amount of information in every NDA that is not relevant to my task in this case.
Q. Did you ever sit down at a database and do keyword searches on the documents that were produced in this case that amount to over 10 million pages of documents?
A. I didn't -- I didn't find a situation where I needed to do that.
Q. My question is different.
Did you do it or did you not?

A. No.
Q. And you mentioned that there are lots of documents that aren't relevant to your task in this case. Did --

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A. That's correct.
Q. And what's your task in this case?
A. Well, my task in this case was to review the documents relevant to the -- basically the approval of Mirena and the labeling of Mirena and the background on -- on use of the product, its risk-benefit analysis and IIH, and the information available about IIH, what is IIH and what may or may not cause IIH, and to develop opinions with regard to whether the labeling was adequate and whether the interactions with FDA were appropriate.
Q. And is it -- did I understand you correctly to say that all of the information in the NDA is not necessarily relevant to the task that you have in this case?
A. That's correct.
Q. Okay.
A. There are details -- many details that are not relevant.
Q. Which -- what parts of -- what parts of the NDA would you consider to be not relevant to your task in this case?
A. I think I already pointed out a lot of that. A lot of the CMC details would not make a difference in my opinion. A lot of the -- the raw

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data that's presented for animal studies and clinical studies is not relevant. The -- the detailed sections of statistics and -- and all of the individual studies are not nearly as important to what I need to do as the overview and the FDA analysis of that material.
Q. Is there anything else -- you mentioned the raw data underlining the animal studies, the chemicals, manufacturing, and control information. Is there anything else that's contained in the NDA that you do not consider to be relevant to your task in this case?
A. I'm sure that there's a lot more in that 10 million pages. Those are the things that come to mind as we sit here.

Q. But I'm talking about the NDA, not 10 million pages. Is there anything else other than the CMC information and the raw data underlining the animal studies that you would consider to be not relevant to your task in this case?

MR. IMBROSCIO: Larry, just so it's clear, I think she -- I think she understood your 10 million representation to be your understanding of what's in the NDA. And I know that's probably not what you meant, but I think that was the source

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of her --

MR. JONES: Confusion?

MR. IMBROSCIO: -- confusion on that.

MR. JONES: Yeah.

BY MR. JONES:

Q. No. But, I mean, you know -- you worked at FDA -- the NDAs are huge, but they're -- I don't think they're 10 million pages.

A. Some of them might be.

Q. Okay. So I'm talking -- you reviewed the NDA in this case, right?

A. I reviewed the parts of the NDA that I needed to review. No one at FDA reviews every page of the NDA.

Q. They don't?

A. No.

Q. Not even the team leader?

A. No.

Q. What parts of the NDA did you consider to be not relevant to your task in this case?

A. I think I already answered that question.

Q. Well, if it's only the underlining animal -- the raw data for the animal studies and the CMC information, then you have answered it. If there's anything else, I'm entitled

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to be able to find out.

A. Well, there is also all the raw data. I mean, all the raw data is analyzed in the study reports and it's reviewed at FDA and the information is summarized by the disciplines that are relevant to each section of the NDA.

For purposes of, for instance, a team leader making a recommendation about approval of the product, no team leader is going to review every

page of that NDA. A team leader would look at the reviews of -- the summary reviews of each individual discipline and go into any sections of the NDA that they needed to look at in order to reach their conclusion.

Likewise, with the kind of task that I had before me here, that same sort of thing was the relevant information that needed to be reviewed, not to dig out every animal study, every piece of raw data from anything, but to get the overall big picture and look at the sections that are relevant to the question at hand.

Q. So you didn't -- in this case, for your task in this case, you didn't review any of the underlining raw data contained in the Mirena NDA?

A. As far as I can think right now, there --

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there wasn't any raw data that I needed to go back and look at.

Q. Okay. And I'm just trying to make sure that I'm understanding you correctly.

So for purposes of this case and your analysis of the NDA, you relied upon the individual reviewers who prepared their portions of the NDA?

A. That is largely true.

Q. Okay. How's it -- how's it not largely true?

A. Well, there are things that I might not remember sitting here right now that if -- when you ask me further questions, I may remember and need to discuss. But as far as the big picture of what we're talking about, I'm giving you the information that I can.

Q. Okay. Well, this is my only chance to ask you.

A. I understand that.

Q. Okay?

And, you know, are you going to remember something later that you reviewed?

A. No, not unless you ask me about something different that I need to say, yes, that was something that I know about or that I read.

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Q. How did you prepare for your deposition today?

A. I went back and looked at my review and --

and looked through the information I had previously read. And of course I sat down and talked to the attorneys about the deposition.
Q. And just -- I want to put this out there. I don't ever want to know what you talked to the attorneys about.
A. I understand that, yes.
Q. I can know if you talked to them, how much time you spent with them --
A. Okay.
Q. -- but not -- I don't want to hear about your conversations.
A. Correct. I understand that.
Q. I just wanted to warn you. Okay?
A. Yes.
Q. Yeah. I mean, you've given depositions before.
A. Yes.
Q. You know that, right?
A. Yes.
Q. Okay. When did you -- how many meetings did you have with the attorneys in preparation for

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your deposition today?
A. Two.
Q. Okay. And when did those meetings take place?
A. Yesterday and the day before.
Q. Okay. And how many hours did you meet yesterday?
A. About five, I think.
Q. Okay. And how many hours the day before?
A. I think maybe six or seven.
Q. Okay. And did you review any documents that are not listed in your 37-page report in these two meetings?
A. I don't believe so.
Q. Putting aside your attorneys -- or Bayer's attorneys, did you talk with anyone about your deposition in this case?
A. No.
Q. You mentioned that you had looked at the Fraunfelder deposition transcript and I think the Etminan deposition transcript.
A. Briefly.
Q. Have you looked at any other of Plaintiffs' experts' deposition transcripts besides Fraunfelder and Ross -- or I'm sorry -- Fraunfelder

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and Etminan, but you had mentioned Ross earlier, right?
A. Yes.
Q. Okay.
A. Yes.
Q. See my question was -- I said Ross because I knew that from earlier.
So now, Fraunfelder, Ross, and Etminan, you have looked at those deposition transcripts, right?
A. Yes.
Q. Okay.
MR. JONES: Let's see. Who else has been deposed in this case? Who are we missing? Maggio.
BY MR. JONES:
Q. Did you look at a Dr. Maggio -- John Maggio's deposition transcript?
A. No, I did not see that one.
Q. Okay. And have you reviewed -- do you know who -- sorry. My allergies are getting me today.
MR. IMBROSCIO: This is a bad time to be in with the allergies, I will tell you that.
BY MR. JONES:
Q. Have you -- do you know who the other

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experts that -- are that Bayer has designated for the benign intracranial hypertension cases?
A. Okay. The one that comes to mind is Feigal, that I've heard his name, but I don't know anything about him.
Q. Okay. Well, I might be able to make it a little bit simpler for you. You mentioned Feigal. Do you know Dr. Feigal?
A. No, I do not.
Q. You didn't work with him at FDA?
A. No.
Q. Have you ever talked with him before?
A. Not that I know of.
Q. Huh?
A. Not that I know of.
Q. Have you talked with or otherwise communicated with any of Bayer's experts in these cases?
A. No.

Q. Do you know who Deborah Friedman is?
A. No.
Q. So if you don't know her, I'm taking it you've never talked with her or otherwise communicated with Deborah Friedman?
A. That's correct.

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Q. Since you left FDA, have you ever discussed Mirena with anyone who is employed by FDA?
A. No.
Q. Have you read any of the deposition transcripts of the Plaintiffs in these cases?
A. Any of the deposition transcripts of the Plaintiffs themselves?
Q. Yes, ma'am.
A. I don't believe so.
Q. Okay. And have you ever read any of the deposition transcripts of the health care providers of the Plaintiffs in these cases?
A. I don't believe so.
Q. Have you ever heard of Deborah Friedman?
A. Well, the name sounds familiar and I've seen the -- the request on this asking about Deborah Friedman, but I do not know who Deborah Friedman is.
Q. Okay. Have you ever talked with or otherwise communicated with any of the authors of the medical journal articles that are cited in your report?
A. I don't believe so.
Q. When I say -- when I mention the Rai study, do you understand what I'm referring to?
A. Yes, I do.

00036

Q. Okay. Have you ever, directly or indirectly, for instance, through third parties, communicated with any of the authors of the Rai study?
A. No, I have not.
Q. Are you aware of whether anyone from Bayer has, directly or indirectly, for instance, through third parties, communicated with any of the authors of the Rai study?
MR. IMBROSCIO: Object to the form.
THE WITNESS: That's not totally clear to me, but I know that Bayer provided an analysis of IIH cases and a signal assessment that discussed

that article, and I can't remember clearly whether they had discussed the case with the authors or not.
BY MR. JONES:
Q. Do you have some sort of vague recollection that Bayer, directly or indirectly, communicated with the authors of the Rai study?
A. I'm sorry. I really don't remember.
Q. Are you aware of any efforts by anyone, whether employed by Bayer or not, to write a response to the Rai study for the purposes of having it published?
A. What I'm recalling about the Rai study and

00037

anything that had been written about it was basically contained within the signal analysis that was done in 2015. I don't recall one that was done for purposes of publication.
Q. Okay. So is -- your current knowledge to date is you're not aware of anyone that is planning to write a response to the Rai study for purposes of publication?
A. That's correct.
MR. IMBROSCIO: I'm thinking about it, Larry.
MR. JONES: I'm sorry?
MR. IMBROSCIO: I'm thinking about it.
MR. JONES: I've thought about it. They don't care what lawyers like us think.
BY MR. JONES:
Q. Are you aware of any efforts by anyone to study the potential association between Levonorgestrel and intracranial hypertension pseudotumor cerebri?
MR. IMBROSCIO: Objection. Vague.
THE WITNESS: Can you further clarify?
BY MR. JONES:
Q. Oh, sure. I'll break it down.
Are you aware of any proposed study to be

00038

conducted by Bayer regarding the potential association between Levonorgestrel and benign intracranial hypertension?
A. As I sit here now, I don't recall any information about that.
Q. Okay. And are you aware of any efforts by anyone outside of Bayer to conduct a study regarding

the potential association between Levonorgestrel and benign intracranial hypertension pseudotumor cerebri?
A. Again, I'm not aware of any plans to do that, and I'm not aware of any indication for doing that.
Q. Yet you haven't heard of any studies in the works?
A. No.
MR. IMBROSCIO: What time are we at?
THE REPORTER: 10:00.
MR. JONES: Do you want to take the one-hour break?
MR. IMBROSCIO: Sure.
MR. JONES: Let's go off the record for a break.
THE VIDEOGRAPHER: The time is 10:02. We'll go off the video record.

00039

(A recess was taken.)
THE VIDEOGRAPHER: The time is 10:13. Back on the video record.
BY MR. JONES:
Q. Dr. Hixon, you were at FDA from January 1999 to November 2011; is that correct?
A. That's correct.
Q. Okay. And at the time you left FDA, do you remember what your salary was?
A. At the time I left FDA, I don't remember exactly, but I can give you an approximate number. It was somewhere around 240,000.
Q. Does $231,648 sound right?
A. That's quite possible.
Q. Okay. And if I understood your testimony correctly earlier today, in 2014, 2015, you received between 150- and $200,000 for -- from Bayer for your work in the MDL cases; is that correct?
A. That's correct.
Q. And in this case so far, you've received approximately $54,300, correct?
A. You are including the amount that has not yet been invoiced, correct?
Q. Correct.
A. So that's approximate, yes.

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Q. Okay. And besides -- Bayer --

besides litigation consulting, does your company or you individually do any other type of consulting work?
A. Yes.
Q. And what kind of consulting work do you do?
A. I do a variety of consulting relating to drug development and regulatory issues. Some of that involves helping companies to put together their clinical study reports to submit to FDA or discussing with them particular products that they're interested in bringing to market and what they might need to do in order to accomplish that goal, or doing some due diligence for companies who are looking to acquire either a product or another company and wanting to look into whether there are potential safety issues with the products they have in mind.
I've also worked with brand name companies whose products are going off patent and they're wanting to estimate how long they have before they will have generic competition so that they can appropriately plan their supply chain.
I've worked with some generic companies

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with basic questions about what they need to do to develop their generic product and -- a variety of other issues that aren't coming to mind at the moment. But --
Q. Okay.
A. -- it kind of spans the gamut of new -- new drugs and generic drugs.
Q. And when you're doing that work, what is your billable hourly rate?
A. It's the same as for litigation work, 600 an hour.
Q. And you mentioned that you formed Pharmaceutical Life -- Lifecycle Consulting in December of 2011; is that correct?
A. I think that's correct.
Q. And so 2012 was your first real year working in that business; is that correct?
A. That's correct.
Q. And approximately what were your gross revenues for 2012 for Pharmaceutical Lifecycle Consulting, LLC?
A. Oh, this is approximate, but it was -- it was not more than 200,000.

Q. Okay. And then in 2013, what were the approximate gross revenues for Pharmaceutical

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Lifecycle Consulting, LLC?
A. Somewhere over 300,000, I think. I'm -- I'm not remembering clearly, but that would be my guess.
Q. And what about for 2014?
A. 2014 I think was a little less. I think it was 200-something.
Q. And what about for 2015?
A. I think 2015 was very much the same as 2014. So in the, you know, 250 to 300 range maybe for -- for 2015.
Q. And during 2014 -- during 2014, 2015, were you working as a litigation consultant for anyone other than Bayer on the MDL cases?
MR. IMBROSCIO: I'm just going to object to the form. Object to the grammar, I think.
THE WITNESS: I was doing other work during that time. I believe that I -- if you look at my list of -- of testimonies that are in my -- my report, I believe that I may have testified in some cases in 2014.

BY MR. JONES:
Q. Okay. It looks like -- thanks for referring me to that. It looks like you testified

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in Anderson v. Janssen Pharmaceuticals February 25th, 26th, 2014. Does that sound correct?
A. That sounds correct.
Q. And Royal v. Novartis Pharmaceuticals Corporation June 19th, 2014. Does that sound correct?
A. That sounds correct.
Q. And do you remember approximately how much you were paid for your time testifying in the -- in those two cases in 2014?
A. I wouldn't be able to break down the amount that I was paid for testifying in each of those cases because I had a deposition and then testified for three trials. And I wrote a number of case-specific reports for that overall project, if you will, so I'm not able to break that down.
Q. Okay. So as I understood your testimony,

your company generated approximately 250- to 300,000 in 2015 plus somewhere in the neighborhood of 200,000 in 2014. So giving you the benefit of the doubt, that would be about a half million dollars between 2014 and 2015; is that correct?
A. That's probably correct.
Q. Okay. And of that, your litigation consulting work for Bayer in the MDL cases made up

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approximately 150- to 200,000 of that revenue, correct?
A. 2014 and 2015?
Q. Yes.
A. I believe that's correct.
Q. Okay. And then you also testified in the Anderson v. Janssen Pharmaceuticals and the Royal v. Novartis Pharmaceuticals in 2014, so there's -- there's -- of the -- we'll give you the benefit of the doubt again. Of the $350,000 in remaining gross revenues for those years, some portion of that was for your work in the Janssen and Novartis cases, correct?
A. That's correct.
Q. What percentage of your revenues would you approximate came from litigation consulting in 2014 and 2015 versus your other consulting work?
A. Well, again, I can only guess because I don't have those numbers in front of me. So given that the litigation work takes a lot more of -- a lot more time than the other individual projects, I believe that it's probably somewhere between 80 and 90 percent.
Q. 80 and 90 percent is --
A. Litigation.

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Q. -- litigation consulting?
A. That's correct.
Q. Do you have any employees at Pharmaceutical Lifecycle Consulting, LLC?
A. I do not.
Q. And I have your address as 7304 Carroll Avenue, Number 231; is that correct?
A. That's correct.
Q. And is that a physical office or is that part of the Takoma Postal & Business Center?
A. That's a mailing address.

Q. Okay. So you don't go to work at 7304 Carroll Avenue, Number 231 every day?
A. That's correct. I -- I have an office nearby.
Q. And where is your office located?
A. At 7030 Carroll Avenue.
Q. Is that a home office?
A. No, it is not.
Q. Do you share that office with anyone?
A. It is a -- kind of an office suite where different people rent individual office space, if that makes sense. So the space I rent is my own space, I'm not sharing it with anyone else, but within -- within that space, within the -- within

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the space at that address, there are about six different offices.
Q. Okay. I think we have something like that on the floor above us at our office.
So it's a shared common reception area and then each tenant has their own physical individual office; is that right?
A. That's correct, except that it really doesn't have a reception area as such.
Q. Okay. Does your company have a website?
A. No.
Q. Has it ever had a website?
A. No.
Q. How do your potential clients find you?
A. It's basically all through word of mouth. I know some other people who previously worked at FDA who are consultants and they had more clients than they were able to handle, so when I started consulting, they would refer clients to me when -- when they couldn't handle the work; and just through word of mouth, from my previous consulting work and from other consultants who -- who know the kind of work I'm doing, referring people to me.
Q. And the other consultants that have too much work and refer clients to you, do you pay them

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any sort of referral fee?
A. No.
Q. Have you ever worked for a plaintiff or an individual who alleged that they were injured by a drug or device as a paid litigation consultant?

A. No, I have not done that.
Q. Other than -- well, let me back up.
The Janssen Pharmaceuticals cases, those involved Topamax; is that correct?
A. That's correct.
Q. Have you ever done any litigation consulting for Janssen for products other than Topamax?
MR. IMBROSCIO: I just want to caution the witness that the fact of you consulting as a consulting expert in any litigation is typically not public until you are disclosed, and so I'd ask you to keep that confidentiality in mind as you give your answer on this, if you can answer generally. But, you know, be careful not to reveal any confidences that you -- you must keep given your other relationships. But do your best to answer given that -- given that constraint.
THE WITNESS: Okay. And given that constraint, I -- the answer is no.

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MR. IMBROSCIO: You know what I'm getting at? I don't want her -- I don't know if she is or isn't.
MR. JONES: Right.
MR. IMBROSCIO: I don't want her saying, oh, I'm revealing -- I'm consulting for the blank case and that's news.
MR. JONES: No. Yeah. No, I get you. I'm trying to think of a different way to answer the -- ask the question.
THE WITNESS: And let me go back and just clarify. Did you say any other consulting work or any other litigation work?
BY MR. JONES:
Q. Any other litigation consulting work.
A. Okay.
Q. Without knowing the product -- and I think we're on good ground here -- have you consulted with Janssen on any other litigation -- any other litigation?
A. No.
Q. And the Royal v. Novartis Pharmaceuticals Corporation case, the one in Cook County, Illinois -- do you know which one I'm talking about?
A. Yes, I do.

00049

Q. -- what product did that involve?
A. That involved Tegretol.
Q. Can you spell that?
A. Tegretol, carbamazepine. It's T-e-g --
Q. It doesn't -- the generic name doesn't help me.
A. T-e-g-r-e-t-o-l, Tegretol.
MR. IMBROSCIO: And can you spell the generic name since you've said it --
THE WITNESS: Sure.
MR. IMBROSCIO: -- and it will help her?
THE WITNESS: C-a-r-b-a-m-a-z-i-n-e, carbamazep -- I left something out.
BY MR. JONES:
Q. I was going to call you the spelling bee champion, but -- we wouldn't have known the difference.
A. C-a-r-b-a-m-a-z-e-p-i-n-e.
Q. What is Tegretol?
A. Tegretol is an antiepileptic drug.
Q. And have you done any litigation consulting work for Novartis other than the Tegretol cases -- case?
A. No.
Q. I guess since we're going -- since we've

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started into the testimony, we might as well talk about that a little bit.
You left FDA in November of 2011, right?
A. That's correct.
Q. Why did you leave?
A. I was at a point where the expanding responsibilities of my job and the expanding responsibilities on the home front were no longer compatible and it was time to make a decision, and I made a decision that I needed to have more control over my time so I retired from FDA in order to do something else.
Q. Okay. And you formed your consulting company the next month, correct?
A. That's correct.
Q. And we talked about you're a medical doctor. You're an OB/GYN; is that correct?
A. That's correct. I was trained in both family medicine and obstetrics and gynecology.
Q. Okay. And once you left FDA, did you -- did you start up an active clinical practice?

A. No, I did not.
Q. And do you have an active clinical practice today?
A. No, I do not.

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Q. So you don't -- you don't see any OB/GYN patients?
A. Not now, that's correct.
Q. Okay. And you haven't since November of 2011 when you left FDA; is that correct?
A. I haven't been actively seeing patients since I left private practice at the end of 1998.
Q. Okay. When you formed your new consulting company in December of 2011, did you have any consulting clients lined up?
A. No, I did not.
Q. Do you consult for any companies other than pharmaceutical or medical device companies?
A. I -- I've done some consulting work for a financial firm, basically due diligence work for determining whether the company had adequately evaluated any potential safety issues for a product it was acquiring.
Q. Okay. I'm not sure that -- if I -- if I've asked you this. If I did, I apologize. But do you do or have you done, since you formed your company in December of 2011, any sort of marketing for clients?
A. No, I have not done that.
Q. You don't have any -- well, let me -- I

00052

don't want to assume anything.
Do you send out a newsletter to current or potential clients?
A. No, I do not.
Q. Do you have any prepared materials that would, for instance, includea bio on your experience that you present to potential clients?
A. No.
Q. Do you go to conferences to try to network with potential clients?
A. No. I go to conferences for continuing medical education and that sort of thing, but not for the purpose of networking.
Q. Well, while you're at those conferences, do you network?

MR. IMBROSCIO: Object to the form.
THE WITNESS: Not consciously. It's not my motivation.
BY MR. JONES:
Q. No one wants to be known as the networker. I get it.
A. Oh, I don't know. There are advantages to networking, but --
Q. I don't know. Networking has a bad name anymore.

00053

When you go to these continuing medical education conferences, do you go to dinner with employees from pharmaceutical companies?
A. I haven't, no.
Q. Attend shows with any of them?
A. I have not.
Q. Does FDA have any restrictions on its former employees consulting for pharmaceutical companies after they leave FDA's employment?
A. Yes. And that restriction is -- is basically that a former employee is not allowed to testify in a matter that significantly involves the U.S. Government, where they're either a party or have a substantial interest, meaning a financial interest, basically, in the outcome.
Q. And I appreciate that. My question is a little different. It's a little nuance.
Are there any restrictions on consulting, not litigation consulting necessarily, just consulting?
A. I've included the -- the restrictions. There's a -- a CFR citation in my report about that. And nothing comes to mind at the moment with regard to what you just asked, so if you have a more specific question.

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Q. No. If you're going to rely on what's in your report, we can just go with that.
A. Okay. That's fine.
Q. When were you first contacted by Bayer about potentially testifying in this particular litigation?
MR. IMBROSCIO: Can you just -- can you just clarify, just because of the -- I think you mean probably your -- your litigation as opposed to

Mirena generally. Can you just --
MR. JONES: Yeah. Yes.
MR. IMBROSCIO: -- help her out on that distinction just to cut it off?
BY MR. JONES:
Q. That's where I was going with this particular litigation, but I understand that there may be some confusion. You may have trouble separating the matters out in your mind.
So when did someone from Bayer talk to you about testifying in the -- what we'll call the benign intracranial hypertension pseudotumor cerebri litigation?
A. As far as contacting me and asking me to begin working on that, that would have been, I think, February of this year.

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Q. And just so the record is clear, that's February of 2016?
A. That's correct.
Q. Okay. And were you contacted by an employee of Bayer or were you contacted by one of Bayer's attorneys?
A. I was contacted by an attorney.
Q. During the course of this litigation, the benign intracranial hypertension pseudotumor cerebri litigation --
A. Okay.
Q. -- have you communicated with any Bayer employees?
A. No, I have not.
Q. Okay. Your report says that you testified in the In Re: Topamax Litigation in the Court of Common Pleas, Philadelphia County, Deposition May 1st, 2013; is that correct?
A. If that's what's in my report, that's correct.
Q. Okay.
MR. IMBROSCIO: And the record should reflect that the witness doesn't have a copy of her report in front of her. That may be worth looking at --

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MR. JONES: Right.
BY MR. JONES:
Q. Are you --

MR. IMBROSCIO: -- at some point.
BY MR. JONES:
Q. Are you confused by -- you just are not sure about the date? You remember testifying in that litigation, correct?
A. Yes, I do.
Q. Okay. And from the case style -- which might be too much lawyer lingo. But In Re: Topamax Litigation signals to me that this was some sort of consolidated proceeding of multiple plaintiffs; is that fair?
A. That's correct.
Q. Okay.
A. Yes.
Q. And you testified for the defendant in that case, correct?
A. That's correct.
Q. And that was -- that's Janssen Pharmaceuticals, right?
A. That's correct.
Q. Okay. And I saw a reference to Ortho-McNeil, Janssen Pharmaceuticals. Was that the

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name of the company, or do you have any idea why I would have seen Ortho-McNeil attached to Janssen?
A. I'm not sure why you see that reference. I am aware that both Ortho-McNeil and Janssen are both affiliated in some way with Johnson & Johnson.
Q. Okay.
A. But I don't know the exact relationship between any of them.
Q. Okay. I was just trying to figure out -- I don't know enough about the companies to -- to know whether those are separate companies. Do you know, Ortho --
A. Yes, they are separate companies --
Q. They are.
A. -- but I don't know any further details about those individual companies and their relationships.
Q. Did you -- was your client just Janssen Pharmaceuticals or was your client also Ortho-McNeil; do you remember?
A. Of course my interactions were with the attorneys, and my understanding was that it was Janssen.
Q. Okay. Fair enough. I just -- merely curious about that.

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So the deposition was in 2013, according to your report, May 1st, 2013. So do you have any idea about when you would have begun working on that case?

A. I believe it was sometime in the fall of 2012.

Q. And what were the -- do you remember what the allegations were in that case from the plaintiffs, the folks that claimed they were injured?

A. The allegation was that women who had taken the product during pregnancy had babies with birth defects and they believed that they were caused by the product.

Q. And what was your -- you know, you had mentioned earlier your task in this case. What was your task in that case?

A. My task in that case was to review the regulatory record and -- and the adverse events, and also to review some individual case reports related to times of exposure and -- and the possibility of the time of exposure coinciding with the formation of the birth defect.

Q. And was your -- were your opinions about whether or not the product warnings were sufficient

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to warn the users of these birth defects?

A. It was about the adequacy of the labeling in that regard.

Q. And was it also about whether or not the company complied with FDA regulations?

A. That's correct.

Q. And your opinion was that the warnings were strong enough and the company complied with the regulations?

A. My opinion was that the warnings were appropriate at the time of the event.

Q. So it sounds like your the opinions you gave in that case were pretty similar to your task in this case, your opinions in this case; is that fair to say?

A. I am a little uncomfortable kind of comparing that case and this case because they're different products and they're different cases.

Q. Right.

A. So can you ask that in any other way?
Q. Yeah, I will because that -- that's fair.
Putting -- taking out the product and -- and the injuries allegedly caused in a case, from kind of a global FDA regulatory expert kind of role, your opinions in that case were similar to your

00060
opinions in this case; is that correct?
A. Let me see if I can answer it in a way I'm comfortable with --
Q. Sure.
A. -- because, again, I don't like to be making a comparison between the two cases because -- excuse me -- I would look at each individual case without regard to the other cases.
However, in both cases, I found that the labeling was appropriate --
Q. Okay.
A. -- and that the interactions with FDA were appropriate.
Q. Okay. And do you remember whether any of your opinions were excluded or limited by the court in that case?
A. No, they were not.
MR. JONES: How are we doing on the video?
BY MR. JONES:
Q. Did you testified at some of these Topamax trials, correct?
A. That's correct.
Q. Okay. And you testified, according to this, at the -- is it -- C-z-i-m-m-e-r. Do you remember --

00061
A. Czimmer.
Q. Just Czimmer --
A. Czimmer.
Q. -- silent C?
Okay. You testified in the Czimmer case, according to this, October 28th, 29th, 2013. Does that sound about correct?
A. That sounds correct.
Q. Okay. And were you testifying in that case that you thought the warnings were appropriate and the company's interactions with FDA were appropriate?
A. That's correct.

Q. Okay. And the jury in that case, they disagreed, didn't they?
A. Well --
MR. IMBROSCIO: I'm going to object to the form of the question.
You can --
BY MR. JONES:
Q. You can answer.
A. I -- clearly the jury decided in favor of the plaintiff in that case. However, exactly what the jury disagreed with, I don't know. So whether they were disagreeing with my testimony or they were

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disagreeing with other testimony is not clear.
Q. Do you agree that the jury disagreed that the labeling was adequate and/or the company's interactions with FDA were inadequate?
MR. IMBROSCIO: Object to the form. Compound.
THE WITNESS: Well, insofar that that was a -- a part of the basis for the entire trial and they decided on behalf of the plaintiff, clearly they were disagreeing in general with the -- with the defendant.
BY MR. JONES:
Q. Okay. And according to my research, the jury awarded $562,184.68 in future health care costs and another $3,440,000 for pain and suffering. Is that consistent with your recollection?
A. That's consistent with my recollection, yes.
Q. Okay. And then you next -- the next Topamax case you testified in was Powell v. Janssen Pharmaceuticals. Here it's -- in your report, it says November 12th, November 13th, 2013. Does that sound correct?
A. That's correct.
Q. And you gave the same opinions in the

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Powell case, correct?
A. When you say "the same," I don't know that it was exactly the same, but yes, it was at least similar opinions.
Q. I mean, did you modify your testimony in the two weeks between the Czimmer and the Powell trials?

A. Well, obviously, I didn't say the same words and it was a different situation, but my opinion was still the same as it had been in my report.
Q. Which was that the product labeling was adequate to warn the plaintiff of the alleged risks, correct?
A. That the product labeling was appropriate at the time.
Q. Okay. And that the interactions with FDA at the time of approval were also adequate, correct?
A. That's correct.
Q. And once again, the jury disagreed with you, didn't they?
A. Again, the -- as in the other case, the jury decided in favor of the plaintiff.
Q. The jury -- the jury awarded about $11 million to the plaintiff in that case, correct?

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A. They did.
Q. I think we're coming to the end of the tape, so let's go off the record so he can change tapes.
A. Okay.
THE VIDEOGRAPHER: The time is 10:53 a.m. This is the end of Disc Number 1. We'll go off the video record.
(A recess was taken.)
THE VIDEOGRAPHER: This is the beginning of Disc Number 2 in the deposition of Dr. Dena Hixon. The time is 11:03 a.m. We're back on the video record.
BY MR. JONES:
Q. Dr. Hixon, we're back after a break. Before we went off, we were talking about the cases that you had testified in. The next one on your list is Anderson v. Janssen Pharmaceuticals. And I have that you testified February 25th, 26th, 2014. Does that sound about correct?
A. That sounds correct.
Q. Okay. And did you give the same opinions in the Anderson case that you gave in Powell and Czimmer?
A. Yes.

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Q. Okay. And, again, the jury disagreed with

you in that case, didn't they?
A. And, again, I would say I'm not sure just what the jury disagreed with, but they decided in favor of the plaintiff again.
Q. And they awarded the plaintiff about $3 million in that case; is that correct?
A. I believe that's correct.
Q. Okay. And in the -- in the Topamax cases, isn't it true that the plaintiffs alleged that within a year of approval by the FDA that the company knew of an increased risk for birth defects including cleft palates?
MR. IMBROSCIO: Object to the form.
THE WITNESS: That's what they alleged.
BY MR. JONES:
Q. And isn't it true that the plaintiffs alleged that the pharmaceutical company in that case didn't tell the doctors about that information?
MR. IMBROSCIO: Object to the form.
THE WITNESS: Again, yes, that's what they alleged.
BY MR. JONES:
Q. And isn't it true that the pharmaceutical company claimed that the reports of cleft lip or

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cleft palate never exceeded the background rates after 10 years of experience with the medicine?
A. As far as I recall, that is true.
Q. What is the status of the coordinated Topamax litigation in Pennsylvania? Is it still ongoing?
A. I really don't know for sure what the current status is.
Q. Okay. You've -- it looks like the last time you testified was a little bit over two years ago. You don't have any indications that you're going to be asked to testify again at a future trial?
A. I don't have any indications at this time one way or another about that.
Q. But nothing's on the schedule? There's no scheduled trial date that you're supposed to testify at?
A. I'm not scheduled, as far as I know, to testify.
Q. Okay. Then going to the next case, Royal v. Novartis Pharmaceuticals Corporation, June 19th, 2014. This was the Tegretol case?

A. That's right.
Q. Okay. And you gave a deposition in that

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case?
A. I did, yes.
Q. Okay. And that case -- it looks like that's coming up on two years since you gave the deposition in the Royal case. Did that case ever go to trial?
A. No, it did not.
Q. Okay. Has it settled or is there a trial date that's been scheduled?
A. I understand that it settled at mediation.
Q. Okay. We'll talk about the Mirena MDL in a second, but before we get there, I want to talk about before you were involved with the MDL. Had you ever worked with any of the attorneys at Shook Hardy & Bacon?
A. No, I had not.
Q. Okay. And had you ever worked with any of the attorneys at the Goldman Ismail firm?
A. No, I had not.
Q. And had you ever worked with any attorneys at the Covington & Burling firm?
A. Not that I recall.
Q. Okay. What about a law firm called Eckert Seamans? Have you ever worked with them before?
A. I don't remember them.

00068
Q. Going back to the Royal case for a second. Do you remember what the plaintiffs alleged in that case?
A. Excuse me. The plaintiffs alleged that the company had not adequately warned about the potential for Tegretol to result in -- for the use of Tegretol to result in blindness.
Q. Okay. And do you remember anything else about what the plaintiffs alleged in that case?
A. I don't specifically remember the allegations.
Q. Okay. Well, do you remember what your opinions were in the Royal v. Novartis Pharmaceuticals case?
A. My opinions were that the labeling was adequate in that they warned about Stevens-Johnson syndrome which was the cause of the visual impairment.

Q. Did you also testify in that case that the company's interactions with FDA were appropriate?
A. I don't specifically remember whether that was a -- a part of the opinions at that point for that case.
Q. Okay. And your deposition was in June of 2014 in that case. Do you remember approximately when you were hired to work on that litigation?

00069

A. I can only give an estimate. And I believe that that was about three months prior to the deposition. I'm not real sure.
Q. Okay.
MR. JONES: Did you hand me a list of a supplemental reviewed and relied --
MS. NATALE: Yeah. They gave us one copy.
MR. JONES: Oh, wasn't there just a -- wasn't there a single sheet?
MS. NATALE: Yeah, it was a single sheet.
MR. IMBROSCIO: We have other copies. You need some more copies of something?
BY MR. JONES:
Q. Yeah, I just want to look at this supplemental list of materials reviewed, Dena Hixon, that's been handed to you by counsel.
Were these -- were these documents -- did you review these transcripts and depositions and labeling before you signed your 37-page report?
A. No, I did not.
Q. Okay. This is something you've reviewed since you submitted your report?
A. That's correct.
Q. And these aren't cited via footnote in your report; is that correct?

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A. That's correct.
MR. JONES: Let's go -- let's just make that Deposition Exhibit 2 since she looked at it.
(Exhibit 2 was marked for identification and is attached to the transcript.)
MR. IMBROSCIO: Larry, you may have this. Do you mind if I just mark her report so she has it in front of her? You -- you're referring to it from time to time and --
MR. JONES: Yeah.
MR. IMBROSCIO: -- it's useful to have it

in front of her.
MR. JONES: That's fine. I just don't have a copy. I figured --
MR. IMBROSCIO: Okay.
MR. JONES: -- she'd have a copy.
MR. IMBROSCIO: Yeah. Let's go ahead and mark that 3, then, just for good order sake.
(Exhibit 3 was marked for identification and is attached to the transcript.)
MR. IMBROSCIO: There you go.
THE WITNESS: Thank you.
BY MR. JONES:
Q. Now, I understand that you were involved with the Mirena approval decision back in 2000; is

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that correct?
A. That is correct.
Q. Okay. And were you the team leader for that approval?
A. I was.
Q. And other than the 2000 initial approval, did you remain involved with the Mirena product over the course of your remaining career at FDA?
A. No, because I left the division in 2002 so I would not have had any involvement with Mirena after that time.
MR. IMBROSCIO: After 2002, you mean?
MR. JONES: Right.
THE WITNESS: That's correct. Sorry.
MR. IMBROSCIO: That's fine. Just making sure you had it right.
BY MR. JONES:
Q. And tell me, while you were at FDA, were you ever involved in any sort of regulatory activities involving Topamax or Tegretol?
A. I don't believe so.
Q. Okay. But you weren't involved in the approvals of Topamax or Tegretol?
A. That's correct.
Q. Oh, I almost forgot to talk to you about

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the Mirena MDL.
So you are currently an expert in the Mirena -- In Re: Mirena IUD Products Liability Litigation; is that correct?
A. That's correct.

Q. Okay. And it looks like from this you gave deposition testimony on September 22nd, 2015; is that correct? I'm on page 4.
A. I'm just looking for the date.
Yes, that's correct.
Q. Okay. And when were you first contacted to be involved in the In Re: Mirena IUD Products Liability Litigation MDL?
A. I believe that was late in 2013.
Q. And do you remember who contacted you to become involved in that?
A. I believe it was Hunter Ahern at Shook Hardy Bacon.
Q. Okay. When you were at FDA, did you have any social interactions with employees from Bayer?
A. No.
Q. None of them -- none of Bayer employees were your social friends?
A. No.
Q. Okay. Are you -- do you consider any

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employees at Bayer to be your friends today?
A. No.
Q. But when you were at FDA, you did have contact -- business contact with Bayer employees, correct?
A. Yes.
Q. And who would you have -- do you remember the names of some of the folks at Bayer that you would have had contacts with?
A. All I can say is that when I saw the names on some of the deposition transcripts that they were familiar to me. I'm not sure if I personally had had any discussions with them or not.
Q. Okay. What's the -- what are the plaintiffs alleging in the In Re: Mirena IUD Products Liability Litigation?
A. The allegation is primarily that uterine perforations can occur at a time later than the insertion and that that is a separate adverse event that has not been adequately warned of.
Q. Okay. And do I understand correctly that your task in that litigation is focused on the warning aspect of the case versus the mechanism of whether or not it could even occur?
A. That's correct.

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Q. Okay.
A. But in that case, it's very hard to -- to totally separate the -- the mechanism idea from the warning.
Q. Okay. All right. And other than the plaintiffs' allegations that the company has failed to adequately warn about this migration perforation, do they allege any other sort of allegations that you've been retained to testify about?
Let me -- that's kind of a confusing question.
A. That is a confusing question.
Q. Let me simplify it.
A. Okay.
Q. In sum and substance -- I mean, we've talked about in cases you talk about, you've testified about the adequacy of a company's warning that's on their product. And then kind of prong two, as I'll call it, is that the company's interactions with FDA were adequate as well.
Are those the same two prongs that you have been retained to testify about in the Mirena MDL?
A. In general, yes.
Q. Okay.

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A. My role is purely as a regulatory expert, not as a causation expert or as a medical expert or any other role.
Q. Epidemiology expert?
A. Correct.
Q. Okay. And is the same true in this particular case, your -- you've been retained, your task is as a -- a regulatory expert, right?
A. That's correct.
Q. Not as a medical expert, right?
A. Right. My understanding is that I'm here as a regulatory expert.
Q. Okay. Not as an epidemiology expert?
A. That's correct.
Q. Not as a pharmacokinetics expert?
A. That's correct.
Q. Not as an IIH expert?
A. That's correct.
Q. And maybe I should -- I'm sorry. Go on and finish. I didn't mean to interrupt you.
A. I thought that perhaps I should clarify

that although my role is not to be an expert in those fields, I do have some expertise in those fields just by virtue of the kind of work I did at FDA that incorporated those kinds of data into the

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regulation process.
Q. Okay. Well, let me ask the question this way. If you were at a conference of epidemiologists, would you feel comfortable standing up and saying, I am an expert in epidemiology?
A. I would not do that, no.
Q. Okay. You wouldn't feel comfortable doing that?
A. Right. I -- I understand the role of an expert in litigation to be someone who has more knowledge than the average person in that field and therefore can help the jury to understand the application of that kind of data.
Q. And if you were at a conference of neuro-ophthalmologists, would you feel comfortable standing up and saying that you are an expert in benign intracranial hypertension pseudotumor cerebri?
A. Absolutely not.
Q. Okay.
A. But, again, from the point of view of being able to explain this kind of event and -- and the FDA use of that data, yes.
Q. What are the symptoms of pseudotumor cerebri?

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A. The most common symptoms are headache or a change in pattern or severity of preexisting headaches or -- and/or visual -- it's most often described as visual obscuration. So visual changes at any rate.
Q. Okay. Anything else?
A. Well, are you -- you asked about symptoms, so are you including signs as well as symptoms?
Q. Sure, signs --
A. So --
Q. What are the signs and symptoms of --
A. Well, symptoms are what the patient would notice and complain about, and signs are what the physician would notice on examination. So the predominant sign of intracranial hypertension,

including, you said, pseudotumor cerebri, the -- the cardinal sign would be a finding of papilledema on examining the eyes.
Q. Okay. Any other signs of pseudotumor cerebri?
A. Clearly elevated intracranial pressure, which is generally something that requires a lumbar puncture in order to know about that.
Q. Okay. Any others?
A. Those are the primary ones that come to

00078

mind.
Q. Okay. So --
A. There are probably others.
Q. -- those were the signs, you said?
A. Well --
Q. Versus the symptoms?
A. -- first was the symptoms and the second was the signs.
Q. Okay. So --
A. The signs are what are found on examination.
Q. Okay. So let's go back to the symptoms, then. Other than headache, visual obscurations, what are the other symptoms of pseudotumor cerebri?
A. They aren't coming to mind at the moment.
Q. Okay. What's the cause of pseudotumor cerebri?
A. It's unknown.
Q. What are the risk factors of pseudotumor cerebri?
A. Okay. The only risk factors that have been demonstrated are female sex, childbearing age, overweight or obesity, and recent weight gain, recent significant weight gain.
Q. Okay. Any others?

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A. There has been some suggestion of various drugs that may possibly be associated, but in general, the -- the studies that have been published haven't really shown strong evidence of that.
Q. Is there a difference between a risk factor and an association?
A. Well, a risk factor isn't necessarily a causal factor, but it is basically a strong enough association that one would -- would correlate the --

the finding with -- with those factors. So the finding of pseudotumor cerebri is often correlated with women of childbearing age who are overweight or obese and/or have had recent significant weight gain.

Q. You agree that obesity doesn't cause pseudotumor cerebri, correct?

A. I don't believe anybody knows the answer to that. There's an association there, but the mechanism of -- that causes pseudotumor cerebri, to my understanding, is not known.

Q. Do you know why obesity -- what mechanism makes obesity a risk factor for pseudotumor cerebri?

A. That is not known, to my knowledge.

Q. What -- you mentioned that -- strike that. Do you know what percentage of obese or

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overweight women of childbearing age in the United States develop pseudotumor cerebri?

A. So the available information suggests that it's approximately 19 or 20 per hundred thousand per year of obese or overweight women of childbearing age.

Q. And what study are you getting that from? Is it the Durcan study?

A. No, I don't -- give me one minute. Okay. It was the Durcan study. And I believe similar numbers have been reported in the Wall and Lee studies.

Q. And do you know how many individuals participated in the Durcan study?

A. I don't remember the population that was evaluated in the Durcan study, but that certainly was not the kind of trial where people were selected to enroll in the trial and followed over time. That was more of an epidemiological population study.

Q. So you don't remember how many people were involved in that study?

A. No, I'm sorry, I don't.

Q. Do you remember how the information was gathered from the study participants?

A. Do you have a copy of the Durcan study

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available?

Q. No.

A. Well, my recall of the Durcan study, I

believe this is the -- the study where queries were sent to all of the neurologists, I think, in the state of Iowa and also in the state of Louisiana, and they asked for information about the number of patients that -- that the physicians had seen with the diagnosis of -- of idiopathic intracranial hypertension. And they continued to follow up over a period of time with similar queries to the physicians and they compared those results to the population in those states.

Q. Do you remember what the response rate was from the physicians?

A. I don't remember exactly what the response rate was, but the authors were comfortable with the results they got because of the -- the follow-up. And they discovered from -- from follow-ups that the physicians who hadn't responded -- in general they hadn't responded because they hadn't seen any patients with that diagnosis. And they felt that -- that their methods of follow-up had been adequate to -- to give that determination.

Q. So the Durcan study authors sent out

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questionnaires to health care providers seeking information about cases of pseudotumor cerebri that they'd seen. Is that a fair representation of what your understanding is?

A. Specifically to the health care providers who would have managed patients with that diagnosis.

Q. Is there anything wrong with sending out questionnaires as part of a study?

A. Well, clearly there are different methods to do studies, but this kind of study is a -- you know, it's looking -- it's looking for rates within the population. And when this study was done -- my understanding is that this was at a time when there were not the same kind of large databases available that we have now to be able to gather this kind of information and that that was probably the -- the best method they had to do it.

But, yes, of course there are always some drawbacks to any study. And within this study, one would be concerned about lack of response from some doctors.

Q. But you still consider this to be good, sound scientific evidence?

A. Well, all of the -- that's not the only study that has given similar results with regard to

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the population incidence of -- of -- of idiopathic intracranial hypertension.

Q. My question is different.

Do you consider the Durcan study to be sound scientific evidence to support the proposition that you've cited in the expert report you've tendered in this case?

A. And what I'm saying by mentioning that there are other studies is that, yes, I think that's sound science. I think any study needs to be confirmed with other studies, and I think we have that in this case because there were multiple studies. There have been multiple studies that have presented similar results.

Q. Isn't it true that actually the ranges are kind of all over the board?

MR. IMBROSCIO: Object to the form. Vague.

THE WITNESS: Well, the ranges vary somewhat, but the studies have pointed out, for instance, that the rates within the general population are about one per hundred thousand. And certainly in some other countries they are somewhat different, because they're somewhat lower in Japan and somewhat higher in Benghazi.

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In women of childbearing age, the rate is about three to four per hundred thousand. And when that -- when the population considered includes only women who are 10 percent or more above their ideal weight, it is in the range of maybe 15 -- I think 15 was the number that was given -- per hundred thousand. And in women who are 20 percent or more above their ideal weight, it is about 19 per hundred thousand women.

BY MR. JONES:

Q. In the Durcan study, were any controls used by the authors?

A. I'm sorry. You would have to give me that -- that paper to review again because I don't remember the -- the details of that study.

Q. Are the details of the studies that you review and rely upon for purposes of presenting an expert report, are the details important?

MR. IMBROSCIO: Object to the form.

Argumentative.
THE WITNESS: You know what, in -- in these cases, you have to look at the details of the study or you don't know what they did, or there are a lot of confounders that can be present in these studies. So yes.

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BY MR. JONES:
Q. Are the details important?
A. Yes, they are.
Q. Okay. In the Durcan study, did they control for the confounder of women who were using contraceptive products?
MR. IMBROSCIO: Object to the form.
THE WITNESS: Again, if you can show me that article, I can better remember the details.
BY MR. JONES:
Q. Ma'am, with all due respect, you're the expert. Do you remember the details of the studies that you've relied upon in your expert report?
MR. IMBROSCIO: Objection.
THE WITNESS: I have not committed those to memory.
Sorry.
MR. IMBROSCIO: Objection. Argumentative. The witness has answered.
BY MR. JONES:
Q. What were some of the other studies that you referred to for your conclusion that obesity and overweight is a proven risk factor for pseudotumor cerebri?
A. The Lee and Wall -- it's not really a

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study, but it's a Lee and Wall publication in UpToDate 2015 and --
Q. Which footnote are you referring to?
A. Footnote 134.
Q. Okay. Let me ask you a question about Lee and Wall. Did -- these authors, did they do their own epidemiology study in this article?
A. Again, if you can provide me with those articles, I can better remember the details of the articles.
Q. But you don't remember it as you sit here right now?
A. No, I have not committed them to memory.

Q. What other studies do you rely upon for your conclusion that obesity and overweight and recent weight gain are proven associations with the development of pseudotumor cerebri?
A. Well, there's footnote 135, the Daniels study. There's footnote 136, the Ko study -- or I should say the presentation. I think there may be some others that aren't coming to mind at the moment, but --
Q. Okay. Well, let's go to -- let's go to footnote 135, the Daniels Profiles of Obesity, Weight Gain and Quality of Life in Idiopathic

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Intracranial Hypertension. Did that author conduct an epidemiology study?
A. I'm sorry. I'm not remembering the details of how that -- how that was done, and I would appreciate it if you could provide me the article.
Q. Footnote 136, the Ko Weight Gain and Recurrence in Idiopathic Intracranial Hypertension, a Case Control Study, can you tell me how many individuals were studied in that case control study?
A. I have not committed that to memory.
Q. Do you know how many participants were involved in that study?
A. I don't remember that.
Q. Do you know what the methods of that study were?
A. Well, it was clearly a case control study according to its title.
Q. How did they gather the information in their case control study?
A. If you can give me the article, I will be glad to refresh my memory on that.
Q. Have you reviewed any other epidemiology --
MR. IMBROSCIO: Just so the record is

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clear, you are declining her request for a copy of the article?
MR. JONES: It's not my responsibility.
MR. IMBROSCIO: Okay. That's fine.
That's fine.
BY MR. JONES:
Q. Any other epidemiology studies that you've

reviewed that support your conclusion that obesity, overweight, and recent weight gain are proven associations or risk factors for the development of pseudotumor cerebri?
A. Give me a minute. I want to look at -- at my reference list and at my review.
Let me read to you from my report because I think this summarizes the data from those studies.
Q. What page are you reading from?
A. I'm on page 21.
So although the overall annual incidence of IIH was estimated to be approximately 1 per 100,000 person-years in the general population, based on data from 30 years ago, IIH is markedly more common in women of childbearing age (approximately 3.5 per hundred thousand), and most common in the subset of those women who are overweight, obese, or have experienced recent weight

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gain. One study found that women between ages 20 and 44 who were 10 percent or more over ideal body weight had an incidence rate of 14.85 per hundred thousand women-years, and that similarly aged women who were 20 percent or more over ideal weight had an incidence rate of 19.3 per hundred thousand women. Other studies have yielded similar findings, and a prospective study of 50 patients diagnosed with IIH found that 94 percent of them were obese.
MR. IMBROSCIO: If you can slow it down for the court reporter.
THE WITNESS: I'm sorry.
MR. IMBROSCIO: She's having a tough time keeping up. She's going fast.
THE WITNESS: Thank you.
Epidemiological -- epidemiology studies have consistently found excess weight to be a risk factor for developing IIH, and recent weight gain appears to be an independent risk factor. As the U.S. population has become heavier in the decades since the original 1 in 100,000 person-years incidence rate was calculated, one would expect a higher overall incidence rate of IIH in the general population. Interestingly, while systemic estrogen levels tend to be high in obese women, progesterone

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levels tend to be lower.

And the footnotes in all of that are footnote 132 through footnote 137. So we have references from Durcan, Wall, Lee, Daniels, Ko, and Yeung.

BY MR. JONES:

Q. Okay. And we've talked about all of those except for footnote 133, Idiopathic Intracranial Hypertension. A Prospective Study of 50 Patients.

Do you -- do you know how the study authors gathered the information about the 50 patients in the prospective study cited in footnote 133?

A. Well, this basically -- in my report, I said that a prospective study of 50 patients who had already been diagnosed with IIH found that 94 percent of them were obese.

Q. Okay.

A. So it's looking at patients who already have that diagnosis and determining what their characteristics are.

Q. And where do -- where do the authors of this study get their information on these 50 patients?

A. Again, I believe that is in the article,

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but I don't have the article in front of me. So if I could have the article, I can provide that information.

Q. Did they use any case controls in this study that's referenced in footnote 133?

A. This is not describing a case control study. It's describing a prospective study of the -- the patients with IIH.

Q. Okay. And do you know whether the authors Wall and George, did they use their files involving their patients or did they seek information about patients from other health care providers?

A. It's hard to remember, having read many different articles, what came from which article, but Wall was also an author in the Lee and Wall study in UpToDate. And they have provided a summary of information from other studies as well as their own.

Q. What other studies did they provide a summary of in this article?

A. I have not committed that to memory.

Q. Okay. And let's talk about footnote number 137, the Yeung, Y-e-u-n-g, Adiposity and Sex

Hormones Across the Menstrual Cycle: the BioCycle Study. Tell me about the BioCycle study.

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A. Well, that was the study that looked at systemic levels of estrogen and of progesterone in obese women. And it showed that the levels of estrogen were higher in obese women, and it is well known that fatty tissue produces estrogen. But it also showed that progesterone levels were lower, which goes against the -- the suggestion that it's the progesterone in IIH that might be responsible for women who have developed IIH while using Norplant.

Q. Okay. And did you provide me with any information different than the sentence that you wrote citing to footnote 137 where you say: Interestingly, while systemic estrogen levels tend to be higher in obese women, progesterone levels tend to be lower? Did you -- in your answer, did you provide me with any information that's different about that study or expands upon what happened in that study than what's in that sentence?

A. No, I didn't. And I would be happy to do that if I have -- if you can provide me with a copy of that.

Q. Was -- the BioCycle study, was that a PK study?

A. I don't remember.

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Q. You don't know what kind of equipment may have been used to test systemic estrogen levels or progesterone levels in the BioCycle study in footnote 137?

A. Well, the way to find out about the systemic levels is to draw blood and measure it.

Q. Using -- what kind of equipment did they use, did these authors use in this study?

A. They would have had to use the analytical study -- the analytical equipment just the same as what is done in a PK study, but I don't remember any further details about -- about the design of that study.

Q. And you'd agree, wouldn't you, that Levonorgestrel is a potent synthetic progestin, correct?

A. I agree with that.

Q. Okay. And the sentence you cite doesn't talk about a synthetic progestin, does it?
A. That's correct, but synthetic progestins were developed to mimic the effects of natural progesterone.
Q. Isn't it true that Levonorgestrel and synthetic progestins are much more potent than natural progesterone?

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A. They are more potent, yes, but one has to keep into consideration that the amounts that are used are -- are smaller, and therefore using a smaller amount of a synthetic progestin would give systemic amounts that are similar to those produced by a larger amount of natural progesterone.
Q. Right.
A. So it's all -- it's all a matter of dose-response.
Q. Are you a sex hormone expert?
MR. IMBROSCIO: Object to the form.
THE WITNESS: I am not specifically a sex hormone expert, but I certainly have had a significant amount of experience reviewing hormones for women's reproductive health care at FDA.
BY MR. JONES:
Q. When you were at FDA, did you -- were you ever responsible for the pharmacology reviews involving products that contained female sex hormones?
A. Again, I wasn't responsible for the pharmacology reviews except to review the summary reviews and take those into account in recommending approvals or other actions.
MR. JONES: All right. Let's break for

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lunch.
THE VIDEOGRAPHER: The time is 11:55 a.m. We'll go off the video record.
(A lunch recess was taken from 11:55 to 1:08 p.m.)

A F T E R N O O N S E S S I O N
THE VIDEOGRAPHER: The time is 1:08 p.m. We're back on the video record.
MR. JONES: Dr. Hixon, welcome back from lunch. At this time, I think that I don't have any

00096
additional questions for you.
MR. IMBROSCIO: Okay. And we have no questions. Thank you very much.
MR. JONES: That was fast.
MS. PALEY: That's good, right?
THE VIDEOGRAPHER: Hold on -- hold on just a second.
The time is 1:08 p.m. This is the end of Disc Number 2 and the end of the video deposition. We'll go off the video record.
(Off the record at 1:08 p.m.)

ACKNOWLEDGMENT OF DEPONENT

I, DENA R. HIXON, M.D., do hereby acknowledge that I have read and examined the foregoing testimony, and the same is a true, correct and complete

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transcription of the testimony given by me and any corrections appear on the attached Errata sheet signed by me.

_____ _____
(DATE) (SIGNATURE)

CERTIFICATE OF NOTARY PUBLIC

I, Samara J. Zink, the officer before whom the foregoing deposition was taken, do hereby certify that the witness whose testimony appears in the foregoing deposition was duly sworn by me to

00098

testify to the truth, the whole truth, and nothing but the truth concerning the matters in this case.

I further certify that the foregoing transcript is a true and correct transcript of my original stenographic notes.

I further certify that I am neither attorney or counsel, nor related to or employed by any of the parties to the action in which this deposition is taken; and furthermore, that I am not a relative or employee of any attorney or counsel employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

_____
Samara J. Zink
Notary Public in and for the
District of Columbia

My commission expires: October 14, 2016

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E R R A T A S H E E T

IN RE: Copley v. Bayer Healthcare

WITNESS: DENA R. HIXON, M.D.

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E R R A T A S H E E T

IN RE: Copley v. Bayer Healthcare

WITNESS: DENA R. HIXON, M.D.

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